UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES ex rel. STEVEN J. BANDER, M.D.,	)	
Relator,	)	Cause No. 4:01CV00553 DDN
v.	)	[redacted]
GAMBRO HEALTHCARE U.S., INC.,	)	**JURY TRIAL DEMANDED**
Defendant.	)	

SECOND AMENDED COMPLAINT

Relator Steven J. Bander, M.D. ("Relator" or "Dr. Bander"), on behalf of the United States, for his complaint against defendant Gambro Healthcare U.S., Inc. ("Gambro"), states as follows:

Introduction

1. Defendant Gambro Healthcare U.S., Inc. ("Gambro") is now and was for all times relevant to this action, a for-profit corporation organized under the laws of the State of Tennessee with its principal place of business in Nashville, Tennessee. Gambro does business throughout the State of Missouri, including in the Eastern District.

2. Both directly and through its subsidiaries, Gambro provides outpatient renal dialysis services for patients with end stage renal disease ("ESRD"). Although the subsidiaries may be nominally separate companies and may be organized pursuant to the laws of different states, Gambro directly controls virtually all

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operations of the subsidiaries. Gambro uses a centralized computer billing system for all subsidiaries. Employees at all centers, and at the corporate level, are paid through a centralized payroll system. Gambro promulgates the subsidiaries' policies and procedures regarding personnel, center management, and treatment. Gambro and the subsidiaries have a single corporate management structure.

3. Prior to 1995, many of Gambro's current dialysis centers were owned by various individuals and corporations across the country. In 1995, Gambro began an aggressive campaign to purchase these independently owned centers and centralize their operations within Gambro. To date, Gambro's largest acquisition was of Vivra Renal Care, Inc. ("Vivra"), which operated approximately 250 dialysis centers, in 1997.

4. Relator Steven J. Bander, M.D. ("Relator") was the chief medical officer of Gambro from 1995 until December 31, 2000. As part of his duties, he oversaw medical and nursing services at outpatient dialysis centers across the United States. Dr. Bander performed site inspections, including chart reviews, developed treatment protocols and training programs for use by center staff, and had primary responsibility for the development of corporate medical policy.

5. This action is brought pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, the Fraud & Abuse Statutes, 42 U.S.C. §§ 1320a-7a & -7b, and the Stark Law, 42 U.S.C. § 1395nn.

6. The False Claims Act provides, inter alia, that any person who knowingly submits a false or fraudulent claim to the federal government for

payment or approval is liable to the Government for a civil penalty of not less than $5500.00 and not more than $11,000.00 for each claim, plus three times the amount of the false claim. 31 U.S.C. § 3729(a). Suits brought under the Act may include false claims made within six years of the date of filing. The Act also permits assessment of the civil penalty even without proof of specific damages. Rex Trailer Co. v. U.S., 350 U.S. 148 (1956).

7. Under the Act, a person ("relator") with knowledge of a false or fraudulent claim against the Government may bring an action against the false claimant on behalf of the Government and himself. Such an action must be filed under seal, without service on the defendant, for sixty days. The seal period is designed to permit the Government to (1) pursue its own investigation of the matter without the defendant's knowledge of the suit and (2) determine whether to join and take over prosecution of the suit. At the time the suit is filed, the relator must provide a written statement of all material evidence in his possession to the U.S. Attorney General. 31 U.S.C. § 3730.

8. Pursuant to the requirements of 31 U.S.C. § 3730(a)(2) and simultaneous with the filing of this complaint, Relator has provided a written statement of all material evidence in his possession to the U.S. Attorney General and the U.S. Attorney for the Eastern District of Missouri.

9. The Fraud and Abuse Statutes, in relevant part, make it illegal to knowingly and willfully solicit or receive any type of remuneration, including a rebate, in return for purchasing, leasing, ordering, arranging for, or recommending

any good, facility, service, or item for which Medicare may pay in whole or in part. 42 U.S.C. §§ 1320-7b(b)(1) & -7a(a)(7). Section 1320a-7b provides for criminal penalties, while § 1320a-7a provides for civil monetary penalties. Most rebates and discounts on Medicare-reimbursed items violate the Fraud and Abuse Statutes. However, if the rebate or discount is properly reported and passed on to Medicare, it may fall within a "safe harbor" of protected activity. 42 U.S.C. § 1320a-7b(b)(3)(A).

10. The Stark Law prohibits referrals to a facility by a physician who has a financial relationship – defined as an ownership interest or compensation arrangement – with the facility. 42 U.S.C. § 1395nn(a). Facilities are barred from submitting claims to Medicare for services provided pursuant to such referrals. Id. Contractual relationships for personal services are not considered compensation arrangements if and only if (1) the arrangement is in writing and specifies all services to be provided by the physician, (2) the services are reasonable and necessary, (3) the arrangement is for at least one year, and (4) the compensation is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of referrals. 42 U.S.C. § 1395nn(e)(3)(A). The Law provides for civil monetary penalties and exclusion of a provider from the Medicare program for such claims. 42 U.S.C. § 1395nn(g).

11. Venue under the False Claims Act is proper in any judicial district in which the defendant can be found, resides, transacts business, or in which any false or fraudulent claim occurred. 31 U.S.C. § 3732(a). Because Gambro does business in the Eastern District of Missouri, venue in this district is proper.

Count I

Fraudulent Billing for Method II Supplies

12. Relator adopts paragraphs 1-11 as and for paragraph 12.

13. By failing to abide by conditions of payment for durable medical equipment and supply companies and by providing Method II patients with supplies (discussed below) through its dialysis facilities, Gambro has submitted false claims to Medicare for supplies and services for which it was not entitled to reimbursement.

14. Patients who receive dialysis at home (almost always through peritoneal, rather than hemo-, dialysis) have two options for reimbursement of supplies and services. Under Method I, an outpatient dialysis facility provides the patient with comprehensive equipment, supplies and necessary support services (backup dialysis, education and monitoring). The dialysis facility receives reimbursement ("the composite rate") from Medicare. Renal Dialysis Facility Manual (RDFM) § 318(B). Under Method II, the patient deals directly with a supplier to obtain necessary supplies and equipment. Id. The supplier must have a written contract with a dialysis facility within the patient's geographical area to provide support services and backup dialysis. Id. The supplier may not provide support services itself, nor may the dialysis facility provide equipment or most supplies. 42 C.F.R. § 410.52; Provider Reimbursement Manual (PRM) § 2740(B). Medicare reimburses the supplier for supplies and the dialysis facility for support services. Id. The total reimbursement rate is higher for Method II than Method I,

both because the reimbursement is divided between two entities (each of which has overhead costs) and because the cost of supplies to an individual is higher than the cost of supplies to a comprehensive dialysis facility.

15. Moreover, Method II supply companies are required to meet regulations applicable to durable medical equipment, prosthetics, orthotics and supply (DMEPOS) companies. As a condition of payment, suppliers are, among other things, required to: (1) fill orders from their own inventory; (2) deliver items to patients; (3) honor all warranties, express and implied; (4) answer patient questions about equipment; (5) make repairs directly or through service contracts with another company; (6) accept return of substandard items; and (7) maintain a physical facility on an appropriate site. 42 C.F.R. § 424.57(c). Suppliers are required to certify compliance with these requirements before they can be paid by Medicare. Id.

16. Further, compliance with all federal, state and local laws and regulations is a condition of coverage for dialysis reimbursement. 42 C.F.R. § 405.2135.

17. Since at least 1997, Gambro has provided equipment and supplies to Method II patients through Gambro Supply Corporation ("GSC"), an allegedly separate DMEPOS, which is really a billing conduit for equipment and supplies provided to Method II patients by Gambro's dialysis facilities.

18. Despite its certifications to the contrary, Gambro has failed to operate GSC as a legitimate DMEPOS, separate from its dialysis facilities, in that:

a. The GSC location in a given area has the same physical address as the dialysis facility providing the support services.

b. The GSC location in a given area has the same telephone number as the dialysis facility providing the support services.

c. GSC uses the same billing department as the dialysis facilities.

d. GSC does not honor warranties, express or implied, for the supplies and equipment it provides.

e. GSC does not maintain and repair, nor does it have a contract for maintenance and repair of, items provided to patients.

f. Orders placed through GSC are drop-shipped to the patient from the manufacturer, rather than from GSC inventory.

g. GSC does not accept return of substandard or unsuitable items from patients.

h. GSC does not answer questions or complaints from patients regarding items sold or rented to them.

i. GSC does not have written contracts with dialysis centers to provide support services for Method II patients.

19. Because Gambro and/or GSC have falsely certified to Medicare that they were in compliance with all applicable laws and regulations while they were, in fact, violating 42 C.F.R. § 424.57 and the other regulations governing dialysis facilities and suppliers under Method II, Gambro and/or GSC have violated 31

U.S.C. § 3729 in that they knowingly submitted false claims to Medicare for supplies and services provided to Method II patients.

20. Gambro is aware that its operation of GSC is in violation of Medicare regulations and, at one point, drafted a plan for compliance. However, the plan was never implemented.

21. Gambro violated 31 U.S.C. § 3729 in that it knowingly submitted claims for reimbursement of Method II equipment and supplies from GSC, a non-compliant DMEPOS company serving as a billing conduit for Gambro's dialysis facilities, and claims for Method II support services from its dialysis facilities, all in violation of applicable law and regulations.

22. As a result of its violations of 31 U.S.C. § 3729 in regard to Method II supplies, Gambro has submitted and continues to submit false claims to Medicare in the approximate amount of $26,000,000.00 per year.

WHEREFORE, Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro and/or GSC for each and every false claim set forth herein, as provided by 31 U.S.C. § 3729(a);

(2) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

(3) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(4) Exclude Gambro and/or GSC from participation in federal health care programs; and

(5) For such other and further relief as this Court deems just and proper.

Count II

Fraudulent Billing for Method II Antibiotics

23. Relator adopts paragraphs 1-22 as and for paragraph 23.

24. Gambro and/or GSC have knowingly submitted false claims to Medicare for reimbursement of Method II supplies that are required to include antibiotics, even though the antibiotics were not included.

25. Under Method II, Medicare covers a variety of dialysis supplies, including some medications, under a reimbursement cap. The cap is the maximum amount a supplier can charge Medicare each month for all the supplies a patient generally needs for home dialysis. PRM § 2710.2. Only certain supplies and medications, used under special conditions, may be billed separately. Id.

26. Home dialysis patients using peritoneal dialysis are very susceptible to peritonitis, a potentially life threatening infection. Because of this, Medicare requires that Method II suppliers include antibiotics for home treatment of peritonitis in the standard supplies covered under the payment cap. PRM § 2710.2(B). They may not be billed separately. Antibiotics administered to the patient at the dialysis center, however, are separately billable. PRM § 2711.2.

27. Since 1997, Gambro and/or GSC have failed to include antibiotics with standard supplies shipped to Method II patients.

28. Instead, when home dialysis patients experience symptoms of peritonitis, Gambro instructs them to come into the dialysis center rather than having GSC provide the antibiotics as required. In some cases, the patient is given a prescription for antibiotics, which must then be filled at a pharmacy at the patient's expense without reimbursement by Medicare. The remaining patients are given intravenous antibiotics at the center, which Gambro then separately bills to Medicare.

29. Gambro and/or GSC have violated 31 U.S.C. § 3729 in that they have knowingly submitted false claims to Medicare for standard supplies supposed to include antibiotics that were not, in fact, included, and have also submitted claims for unnecessary antibiotics administered at the facility.

30. Gambro and/or GSC have submitted and continue to submit false claims to Medicare for at least 3500 patients not receiving antibiotics per year. The total amount of false claims attributable to unnecessary antibiotic administration at Gambro's dialysis facilities is unknown at this time.

WHEREFORE Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro and/or GSC for each and every false claim set forth herein, as provided by 31 U.S.C. § 3729(a);

(2) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

(3) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(4) Exclude Gambro and/or GSC from participation in federal health care programs; and

(5) For such other and further relief as this Court deems just and proper.

Count III

Fraudulent Billing Under Method II for Emergency Supplies

31. Relator adopts paragraphs 1-30 as and for paragraph 31.

32. Gambro and/or GSC have submitted false claims to Medicare for reimbursement of emergency supply kits they never delivered or documented as delivered to patients.

33. When a patient begins home dialysis on Method II, Medicare will reimburse the supplier for an "emergency kit" delivered to the patient, consisting of a complete one month set of supplies. PRM §2714.5. The patient then has supplies on hand in the event of subsequent shipping or supply problems.

34. Gambro and/or GSC, as DMEPOS companies, are required to separately document delivery of each emergency kit to each patient. Medicare Program Integrity Manual (MPIM) Ch. 5, § 2.1. Moreover, Gambro, as service provider, is required to keep a comprehensive list of all supplies and equipment provided to each home dialysis patient. 42 C.F.R. § 410.52.

35. Since at least 1997, Gambro and/or GSC have failed to document delivery of the emergency kits. Some of these kits were never delivered and it is unclear which of the others were received by patients.

36. Gambro and/or GSC have violated 31 U.S.C. § 3729 in that they have knowingly submitted false claims to Medicare for emergency kits that were either not delivered or not properly documented as delivered, in violation of applicable law and regulations.

37. As a result of their violations of 31 U.S.C. § 3729 in regard to billing for emergency kits, Gambro and/or GSC have submitted and continue to submit false claims to Medicare in the approximate amount of $2,800,000.00 per year.

WHEREFORE Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro and/or GSC for each and every false claim set forth herein, as provided by 31 U.S.C. § 3729(a);

(2) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

(3) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(4) Exclude Gambro and/or GSC from participation in federal health care programs; and

(5) For such other and further relief as this Court deems just and proper.

Count IV

Split Vial Dosing

38. Relator adopts paragraphs 1-11 as and for paragraph 38.

39. Gambro has knowingly submitted false claims to Medicare for reimbursement of vials of medication it did not administer to patients.

40. During dialysis treatment, patients typically receive certain intravenous medications called ancillary medications. The type of ancillary medication varies depending on the patient's medical condition. For every ancillary medication (except EPO, discussed below in Counts V and VI), Medicare reimburses the provider per vial of medication, rather than the actual amount administered. The proper amount of medication administered varies from patient to patient and, in most cases, the amount prescribed by the physician does not constitute a full vial. Because the vials are labeled "single use only" and do not contain preservatives, use of the remaining medication in the vial for another dose presents a risk of infection to the patient. Consequently, good medical practice requires that the remaining potentially contaminated medication be disposed of. This disposal is supposed to be documented.

41. From 1997 until the present, some Gambro dialysis facilities, including facilities that were formerly owned by Vivra Renal Care and Renal Management, Inc., have engaged in "split-vial dosing". Split-vial dosing involves withdrawing the excess medication from a vial rather than disposing of it. The excess medication

from several vials is then combined to create a dose and is administered to the next patient.

42. Gambro then bills Medicare for medication based upon the number of vials that would have been used had the excess been properly disposed of, instead of the far fewer vials actually administered.

43. Gambro's practice of split-vial dosing also violates Medicare regulations for coverage of drugs, which allow for reimbursement only if a drug is necessary for the patient's treatment and is used according to its label or in a manner consistent with good medical practice. 42 C.F.R. § 410.50; Medicare Intermediary Manual (MIM), §§ 3168, 3112.4 & 3101.3.

44. Further, because pharmaceutical regulations in most states prohibit multiple entries into single-use vials, by submitting claims for split-vial doses, Gambro submitted false claims under 42 C.F.R. § 405.2135, which requires compliance with Federal, state and local law as a condition for reimbursement.

45. Gambro violated 31 U.S.C. § 3729 by knowingly submitting false claims to Medicare for the number of vials that would have been used had the dialysis facilities not engaged in split-vial dosing and properly disposed of excess medication, rather than the actual number of vials used.

46. The exact amount of the false claims submitted by Gambro in regard to split-vial dosing is unknown at this time.

WHEREFORE Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro for each and every false claim made by Gambro as a result of split-vial dosing, as provided by 31 U.S.C. § 3729(a);

(2) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

(3) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(4) Exclude Gambro from participation in federal health care programs; and

(5) For such other and further relief as this Court deems just and proper

Count V

Fraudulent Billing for Epoetin Alfa Vial Overfill

47. Relator adopts paragraphs 1-11 and 43 as and for paragraph 47.

48. Gambro has knowingly submitted false claims for Epoetin alfa by administering the medication in an off-label manner and by billing Medicare for more medication than was actually administered.

49. Epoetin alfa ("EPO" or "Epogen") is a synthetic hormone used to treat anemia, which is a complication in nearly all patients with ESRD. Gambro administers EPO to patients at all of its dialysis facilities. EPO is manufactured by Amgen, Inc., which has an exclusive patent on EPO until 2005.

50. EPO is packaged in single-use vials. Consistent with good pharmaceutical practice, each vial contains approximately 16.8% overfill to allow the prescribed dose to be drawn up for delivery. Such overfill is in addition to the labeled dose contained in the vial, and is not intended to be administered to the patient. The purpose of overfill is to ensure that, no matter what type of syringe or needle is used in administration, the vial will produce the labeled quantity of EPO

51. As with ancillary medications (discussed in Count IV, above), EPO does not contain preservatives. To avoid potential infection risks to the patient, the potentially contaminated overfill in a single-use EPO vial should be disposed of after the single dose has been withdrawn. Many states prohibit multiple entries into single-use vials in their pharmaceutical laws and regulations. Because EPO vials are labeled as single-use only, multiple entries into EPO vials are considered "off-label" use and violations of good medical practice.

52. With regard to off-label administration of EPO:

a. From 1993 until its acquisition by Gambro in 1997, Vivra instructed its employees to make multiple entries into single-use-only vials to capture the overfill in EPO vials.

b. In 1997, Gambro issued a written policy standardizing the use of multiple entries into single-use vials for all units, including the ones acquired through Vivra.

c. Overfill from multiple vials is combined to form additional doses of EPO.

d. The additional doses are billed to Medicare as if they came from new vials.

53. Such multiple entries into single use vials are a violation of standard medical practice, state law, and Medicare conditions of coverage for drugs, which require use of medications according to their labels or consistent with good medical practice. See ¶ 43, above. Multiple entries also pose a significant risk of infection to patients.

54. Gambro has violated 31 U.S.C. § 3729 in that it has knowingly submitted claims for EPO administered as described above, even though by doing so it is not in compliance with federal, state and local laws and regulations, nor is it using the drug consistent with its label or good medical practice, both of which are conditions for reimbursement.

55. In addition, since 1997, Gambro employees, in their attempts to use the overfill, systematically administer underdoses of EPO to patients, as evidenced by the fact that some facilities bill for more EPO than is actually contained (i.e., more than 116.8%) in the number of vials used.

56. Gambro is aware of such underdosing and has taken no steps to address it. To the contrary, Gambro management has consistently encouraged dialysis facilities to increase the volume of EPO that is billed per vial.

57. Gambro has violated 31 U.S.C. § 3729 in that it has knowingly submitted false claims for amounts of EPO that it has not administered (and could not possibly have administered) to patients.

58. As a result of the above practices, Gambro has submitted and continues to submit false claims for EPO to Medicare of approximately $30,000,000.00 per year.

WHEREFORE Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro for each and every false claim made by Gambro for administration of EPO vial overfill, as provided by 31 U.S.C. § 3729(a);

(2) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

(3) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(4) Exclude Gambro from participation in federal health care programs; and

(5) For such other and further relief as this Court deems just and proper.

Count VI

Violations of the Fraud and Abuse Statutes Related to EPO

59. Relator adopts paragraphs 1-11, 43 and 47-58 as and for paragraph 59.

60. Gambro has knowingly submitted false claims to Medicare for reimbursement of EPO in that it has received prohibited remuneration (in the form of rebates and in-kind kickbacks) in return for purchasing EPO, while falsely

certifying to Medicare that it was in compliance with all applicable laws and regulations.

61. As noted above, compliance with all applicable laws and regulations is a condition of coverage for reimbursement of dialysis. 42 C.F.R. § 405.2135.

62. Moreover, each year, Gambro and its subsidiaries submit a cost report known as HCFA-265 to the Health Care Finance Administration. HCFA-265 is required from all dialysis facilities that bill to Medicare and includes a certification of Gambro's adherence to federal laws and regulations. Provision of the cost data and the certification in HCFA-265 is a condition of coverage. 42 C.F.R. § 405.2133.

63. Gambro has violated 42 U.S.C. §§ 1320a-7a & -7b in that:

a. Gambro purchases EPO from Amgen at a rebated price of approximately $8.20 to $8.60 per 1000 units.

b. Medicare reimburses Gambro at the rate of $10.00 per 1000 units administered.

c. Gambro has failed to disclose or pass on its Amgen rebate to Medicare, either in its bills for EPO or in HCFA-265.

d. The undisclosed rebate received by Gambro constitutes prohibited remuneration under 42 U.S.C. §§ 1320a-7a & -7b because it is paid by Amgen in exchange for Gambro's purchase of EPO, for which Medicare reimburses Gambro.

64. Gambro has also violated 42 U.S.C. §§ 1320a-7a & -7b in that:

a. Since September 2000, Amgen has provided anemia management training and support to Gambro staff. This service is provided by Amgen without charge to Gambro and saves Gambro some $200,000 per year.

b. Prior to the Amgen program, Gambro had its own anemia management program created by Dr. Bander and others.

c. Under the program created by Dr. Bander, Gambro used less EPO per patient than, but had similar clinical results to, other dialysis providers in the industry.

d. Gambro management repeatedly expressed dissatisfaction with the reduced use of EPO under Dr. Bander's program, stating that the lower usage reduced revenues to Gambro, both in terms of per-vial profit and in terms of ineligibility for greater quantity discounts from Amgen.

e. Since late 2000, when it adopted the Amgen program, Gambro's per-patient EPO usage has increased, without a corresponding increase in clinical outcomes. Cost of EPO per treatment has increased an average of $7.

f. As part of the Amgen anemia management program, Gambro permits Amgen staff to attend confidential quality assurance meetings, in which Amgen staff is permitted to review patient-

specific data without patient knowledge or consent, in violation of 42 C.F.R. § 405.2139 and various state laws.

g. In return for Gambro's purchases of EPO and access to patient records, Amgen also provides Gambro with clinical and sales staff at no charge and expends significant funds entertaining clinic staff and physicians.

h. The anemia management training, clinical and sales staff, and entertainment funds provided to Gambro by Amgen constitute prohibited in-kind remuneration under 42 U.S.C. §§ 1320a-7a & -7b because it is provided in exchange for Gambro's purchase of EPO, for which Gambro is reimbursed by Medicare.

65. Because Gambro has falsely certified that is in compliance with Federal, state and local laws and regulations when in fact it was violating 42 U.S.C. §§ 1320a-7a & -7b, and because such certification is a condition of coverage by Medicare, Gambro violated 31 U.S.C. § 3729 in that it has knowingly submitted false claims for EPO to Medicare.

66. As a result of its violation of 31 U.S.C. § 3729 in regard to EPO, Gambro has submitted and continues to submit false claims to Medicare in the approximate amount of $50,000,000.00 per year. Moreover, the unnecessary increase in each EPO dose, as discussed in paragraph 64, will result in false claims of $30,000,000.00 to $40,000,000.00 per year.

WHEREFORE Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro for each and every false claim set forth herein, as provided by 31 U.S.C. § 3729(a);

(2) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

(3) Assess a civil penalty of $50,000.00 for each act of illegal remuneration, in cash or in kind, as set forth herein, as provided by 42 U.S.C. § 1320a-7a(a);

(4) Award damages in the sum of three times the amount received as illegal remuneration, as set forth herein, as provided by 42 U.S.C. § 1320a-7a(a);

(5) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(6) Exclude Gambro from participation in federal health care programs; and

(7) For such other and further relief as this Court deems just and proper

Count VII

Violations Related to Selection of Vitamin D Analogs

67. Relator adopts paragraphs 1-11, 43 and 61-62 as and for paragraph 67.

68. Gambro has knowingly submitted false claims to Medicare in that it has billed for unnecessary medication and in that it has received prohibited

remuneration (in the form of rebates) in return for purchasing the drug Zemplar, while falsely certifying to Medicare that it was in compliance with applicable law and regulations.

69. Vitamin D analogs are drugs prescribed for dialysis patients for a variety of disorders, including hypocalcemia and secondary hyperparathyroidism. Some 50-60% of dialysis patients receive a vitamin D analog as part of their treatment. Medicare reimburses for two vitamin D analogs, Calcijex and Zemplar. The two are clinically identical for most patients, although Zemplar is more expensive.

70. In 1999, Abbott Laboratories, Inc., the manufacturer of both Calcijex and Zemplar, began a program to encourage providers to use the more profitable Zemplar instead of Calcijex. As part of that program, Abbott offered a rebate to Gambro if it would increase the amount of Zemplar administered to patients.

71. As a result of the rebate, use of Calcijex became even less profitable for Gambro than use of Zemplar, which is 1.9 times more expensive.

72. After the rebate was announced, during 1999 and 2000, Gambro management waged an aggressive campaign to encourage physicians to prescribe Zemplar instead of Calcijex for their patients.

73. As part of the campaign, Gambro's regional vice presidents instructed center managers (usually registered nurses) to contact referring physicians and encourage them to change their patients' medication from Calcijex to Zemplar through a variety of means, including but not limited to representing that Zemplar

was the "preferred drug" for patients requiring vitamin D analogs and representing that Calcijex was being eliminated from Gambro's formulary.

74. Gambro management repeatedly pressured Relator to instruct all physicians at Gambro facilities to use Zemplar instead of Calcijex. Relator refused to do so.

75. Gambro's representation that Calcijex was being eliminated from Gambro's formulary was false and made with the sole purpose of causing physicians to change their patients' prescriptions from Calcijex to Zemplar.

76. Gambro's representation that Zemplar was the "preferred drug" for patients requiring a vitamin D analog was false in that Calcijex and Zemplar are clinically identical for most patients, both in terms of efficacy and side effects.

77. To facilitate changing current patients' medication from Calcijex to Zemplar, Gambro instructed dialysis facility staff to write physician orders documenting the change for each patient's chart. The physician was then requested to sign the order the next time he reviewed the chart.

78. Many of these orders were never signed by the physician, although Gambro began administering Zemplar to the patient. Some orders were signed long after the change in medication had been made. More importantly, none of these orders contained documentation of medical necessity for the change, because all of the changed patients were doing well on the less profitable Calcijex.

79. By making false representations to physicians, Gambro caused said physicians to unnecessarily change patients' medication from Calcijex to Zemplar.

(4) Award damages in the sum of three times the amount received as illegal remuneration as set forth herein, as provided by 42 U.S.C. § 1320a-7a(a);

(5) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(6) Exclude Gambro from participation in federal health care programs; and

(7) For such other and further relief as this Court deems just and proper.

Count VIII

Violations Related to Selection of Iron Supplements

84. Relator adopts paragraphs 1-11, 43 and 61-62 as and for paragraph 84.

85. Gambro has knowingly submitted false claims to Medicare in that it has billed for unnecessary medication and in that it has received prohibited remuneration (in the form of rebates) in return for purchasing Ferrlecit, while falsely certifying to Medicare that it was in compliance with all applicable laws and regulations.

86. As noted in paragraph 49, anemia is a complication in virtually all cases of ESRD. In addition to EPO, about 60% of dialysis patients receive an intravenous iron supplement for anemia. Two iron supplements for which Medicare reimburses are Infed and Ferrlecit. Although Infed may cause more side effects when initially administered to a patient, for patients established on Infed, Infed is clinically identical to Ferrlecit in terms of side effects and efficacy.

87. In 1999, Schein Pharmaceuticals, Inc., the manufacturer of both Infed and Ferrlecit, began a program to encourage providers to use the more profitable Ferrlecit instead of Infed. As part of that program, Schein offered a rebate to Gambro if it would increase the amount of Ferrlecit administered to patients.

88. As a result of the rebate, use of Infed became even less profitable for Gambro than use of Ferrlecit, which is 1.5 times more expensive.

89. After the rate was announced, in 1999 and 2000 Gambro management waged an aggressive campaign to encourage physicians to prescribe Ferrlecit instead of Infed for their patients.

90. As part of the campaign, Gambro's regional vice presidents instructed center managers (usually registered nurses) to contact referring physicians and encourage them to change their patients' medication from Infed to Ferrlecit through a variety of means, including but not limited to representing that Ferrlecit was the "preferred drug" for patients requiring an iron supplement and representing that Infed was being eliminated from Gambro's formulary.

91. Gambro Management repeatedly pressured Relator to instruct all physicians at Gambro facilities to use Ferrlecit instead of Infed. Relator refused to do so.

92. Gambro's representation that Infed was being eliminated from Gambro's formulary was false and made with the sole purpose of causing physicians to change their patients' prescriptions from Infed to Ferrlecit.

93. Gambro's representation that Ferrlecit was the "preferred drug" for patients requiring an iron supplement was false in that Infed and Ferrlecit are clinically identical for patients already established on Infed, both in terms of efficacy and side effects.

94. To facilitate changing current patients' medication from Infed to Ferrlecit, Gambro instructed dialysis facility staff to write physician orders documenting the change for each patient's chart. The physician was then requested to sign the order the next time he reviewed the chart.

95. Many of these orders were never signed by the physician, although Gambro began administering Ferrlecit to the patient. Some orders were signed long after the change in medication had been made. More importantly, none of these orders contained documentation of medical necessity for the change, because all of the changed patients were doing well on the less profitable Infed.

96. By making false representations to physicians, Gambro caused said physicians to unnecessarily change patients' medication from Infed to Ferrlecit.

97. Although it received the rebate from Schein, Gambro did not properly disclose, nor did its costs and charges appropriately reflect, the rebate for Ferrlecit.

98. Gambro has violated 31 U.S.C. § 3729 in that it has submitted claims for unnecessary doses of Ferrlecit.

99. In addition, because Gambro falsely certified that it was in compliance with all laws and regulations when it was in fact violating 42 U.S.C. §§ 1320a-7a & -7b by receiving an illegal rebate, and because such certification is a condition of

Medicare reimbursement, Gambro violated 31 U.S.C. § 3729 in that it knowingly submitted claims for Ferrlecit to Medicare.

100. As a result of its violations of 31 U.S.C. § 3729, Gambro submitted false claims for Ferrlecit to Medicare in the approximate amount of $10,000,000.00. The rebate, which Gambro received from Schein in late 2000, was in the approximate amount of $2,500,000.00.

WHEREFORE Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro for each and every false claim set forth herein, as provided by 31 U.S.C. § 3729(a);

(2) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

(3) Assess a civil penalty of $50,000.00 for each act of illegal remuneration, in cash or in kind, as provided by 42 U.S.C. § 1320a-7a(a);

(4) Award damages in the sum of three times the amount received as illegal remuneration as set forth herein, as provided by 42 U.S.C. § 1320a-7a(a);

(5) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(6) Exclude Gambro from participation in federal health care programs; and

(7) For such other and further relief as this Court deems just and proper.

Count IX

Preemptive Coding

101. Relator adopts paragraphs 1-11 as and for paragraph 101.

102. Gambro has submitted false claims to Medicare in that it has billed for treatments to patients using incorrectly assigned diagnosis codes.

103. Medicare only covers items and services that are reasonable and necessary for the diagnosis and treatment of illness or injury. Because not all treatments are reasonable and necessary for all conditions, correct diagnoses are critical to determine whether or not a treatment is covered by Medicare. The diagnosis must be made by a physician and listed on all Medicare billing forms as a standardized International Classification of Diseases, Ninth Edition, Clinical Modification ("ICD-9") number. Correct ICD-9 codes are vital to proper reimbursement.

104. Since the late 1980s, each Gambro facility has used the same computer software system to track fees for dialysis treatment and medications. Gambro's billing operations are located in Nashville, Tennessee and Alisa Viejo, California.

105. Gambro's software system assigns an ICD-9 code based upon the treatment and medication, rather than the actual diagnosis made by the physician. As a result, all patients receiving a certain treatment regimen receive the same ICD-9 codes, even though they may have different diagnoses.

106. Manual changes of this "hard" or "preemptive" coding are time consuming and difficult. Neither the ability to make manual changes, nor the

requirement for entry of an ICD-9 code, is readily apparent to program users. As a result, few manual changes are actually performed.

107. In all cases, the preemptive ICD-9 code maximizes Medicare reimbursement for a given treatment regimen, regardless of an individual patient's diagnosis or medical necessity.

108. In some cases, the preemptive ICD-9 code permits reimbursement for certain treatments or medications when the patient's actual diagnosis was such that reimbursement would have been denied.

109. Gambro has violated 31 U.S.C. § 3729 in that it has knowingly submitted claims with false and/or incorrectly-assigned ICD-9 codes.

110. As a result of its violations of 31 U.S.C. § 3729 resulting in incorrect ICD-9 coding, Gambro has submitted and continues to submit false claims with incorrect ICD-9 codes to Medicare in the approximate amount of $25,000,000.00 per year. Gambro's total billing using preemptively coded diagnoses, correct and incorrect, amounts to approximately $1,200,000,000.00 per year.

WHEREFORE Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro for each and every false claim set forth herein, as provided by 31 U.S.C. § 3729(a);

(2) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

(3) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(4) Exclude Gambro from participation in federal health care programs; and

(5) For such other and further relief as this Court deems just and proper.

Count X

Financial Relationships with Medical Directors

111. Relator adopts paragraphs 1-11 as and for paragraph 111.

112. Gambro has submitted false claims to Medicare in that it has submitted claims for services to patients referred by physicians with whom it had a financial relationship.

113. Since at least 1997, Gambro has entered into contracts with physicians to serve as medical directors for Gambro's dialysis facilities. Medical directors provide administrative and medical oversight services for the dialysis facilities under their control, and receive compensation of $30,000 to $250,000 per year.

114. When selecting medical directors, Gambro targets physicians who have generated and will generate the largest number of referrals to Gambro from their private practices. Gambro does not consider the medical or administrative expertise of these physicians.

115. Medical director compensation is not based upon the duties, time or expertise required from the medical director, but by the volume and value of

referrals the physician and/or his practice have generated and will generate to Gambro.

116. Medical director compensation is many times higher than the fair market value of the services provided.

117. Gambro has about 500 medical directors throughout the United States, of which some 350 are compensated above fair market value.

118. Further, since at least 1997, Gambro has entered into contracts with certain of the above-referenced medical directors whereby those directors receive increased compensation in exchange for serving as so-called "regional medical directors."

119. Regional medical directors have the same contractual duties as regular medical directors, namely to provide administrative and medical oversight services for the dialysis facilities under their control. Regional medical directors have no additional duties and do not supervise other medical directors.

120. Regional medical directors receive a variety of reimbursement packages, including payment of support staff salaries for their private practices and monetary reimbursement, in addition to compensation as regular medical directors.

121. When selecting regional medical directors, Gambro targets medical directors who have provided and will continue to provide the highest number of referrals to Gambro from their private practices. Gambro does not consider the administrative or medical expertise of these medical directors or their performance as regular medical directors.

122. Because it determines medical director (both regular and regional) compensation by the volume and value of referrals and because the compensation exceeds fair market value, Gambro has a "financial relationship" with its medical directors and, therefore, under 42 U.S.C. § 1395nn, may not bill Medicare for services furnished pursuant to referrals from medical directors.

123. Gambro violated 31 U.S.C. § 3729 in that it knowingly submitted false claims to Medicare for services for which it was not permitted to bill under 42 U.S.C. § 1395nn.

124. As a result of its violation of 31 U.S.C. § 3729 resulting in impermissible billing for services rendered to patients referred by physicians with whom it has a financial relationship, Gambro falsely bills Medicare for $400,000,000.00 per year.

WHEREFORE Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not more than $15,000.00 against defendant Gambro for each and every prohibited financial transaction in exchange for referrals as set forth herein, as provided by 42 U.S.C. § 1395nn;

(2) Assess a civil penalty against defendant Gambro of not more than $100,000.00 for each medical director contract that has a principal purpose of assuring referrals, as provided by 42 U.S.C. § 1395nn;

(3) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro for each and every false claim set forth herein, as provided by 31 U.S.C. § 3729(a);

(4) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. § 3729(a) and 42 U.S.C. § 1395nn, plus interest;

(5) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. § 3730(d);

(6) Exclude Gambro from participation in federal health care programs; and

(7) For such other and further relief as this Court deems just and proper.

Count XI

Violations of the Fraud and Abuse Statutes
Related to Jackson Memorial Hospital

125. Relator adopts paragraphs 1-11 as and for paragraph 125.

126. Gambro has knowingly submitted false claims to Medicare in that it has paid illegal remuneration (in the form of in-kind services) for referrals from Jackson Memorial Hospital, while falsely certifying that it was in compliance with all applicable laws and regulations.

127. Gambro has entered into a contract with Jackson Memorial Hospital in Miami, Florida, whereby Gambro provides inpatient dialysis at no cost to the hospital and Jackson Memorial Hospital refers its outpatients to Gambro dialysis facilities.

128. The provision of no-cost services in exchange for referrals constitutes in-kind remuneration for referrals, which is prohibited under 42 U.S.C. §§1320a-7a &-7b.

129. Because Gambro falsely certified that it was in compliance with all applicable laws and regulations when it was, in fact, providing illegal in-kind remunerations for referrals in violation of 42 U.S.C. §§1320a-7a & -7b, Gambro violated 31 U.S.C. §3729 in that it knowingly submitted false claims to Medicare for services provided pursuant to those referrals.

130. The amount of false claims submitted to Medicare as a result of its violations of 31 U.S.C. §3729 for referrals from Jackson Memorial Hospital is unknown at this time. The value of services provided by Gambro to Jackson Memorial Hospital in exchange for those referrals is in excess of $1,000,000.00 per year.

WHEREFORE, Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro for each and every false claim set forth herein, as provided by 31 U.S.C. §3729(a);

(2) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. §3729(a), plus interest;

(3) Assess a civil penalty of $50,000.00 against defendant Gambro for each act of illegal remuneration, in cash or in kind, as provided by 42 U.S.C. §1320a-7a(a);

(4) Award damages in the sum of three times the amount provided as illegal remuneration as set forth herein, as provided by 42 U.S.C. §1320a-7a(a);

(5) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. §3730(d);

(6) Exclude Gambro from participation in federal health care programs; and

(7) For such other and further relief as this Court deems just and proper.

Count XII

Financial Relationships with Gambro Nephrology Services Physicians

131. Relator adopts paragraphs 1-11 and 113 as and for paragraph 131.

132. Gambro has submitted false claims to Medicare in that it has submitted claims for services to patients referred by physicians with whom it has a financial relationship through Gambro Nephrology Services.

133. Since at least 1997, Gambro has operated Gambro Nephrology Services (GNS), a division of Gambro that provides "practice management services" for nephrology practices across the country. Prior to 1997, Vivra operated a similar division called Vivra Nephrology Partners (VNP).

134. GNS (and, prior to 1997, VNP) enters into contracts with existing nephrology practices whereby, for a percentage of the income, GNS agrees to manage all non-medical aspects of the practice, including billing, payroll, inventory and payment of overhead expenses. GNS also provides benefits (i.e. health insurance, retirement plans) to the practice's employees and physicians.

135. In many cases, GNS pays the physicians a set salary, plus bonuses based on the performance of the practice.

136. In other cases, Gambro has established new nephrology practices, setting up offices and hiring staff and physicians.

137. Physicians in these practices enter into a contract with GNS, whereby the physician agrees to operated the practice in exchange for a guaranteed salary, staff and overhead expenses. Typically, these contracts are for three to five years.

138. In nephrology practices managed or owned by GNS, physician compensation (in terms of both salary and payment for staff and overhead) is not based upon the fair market value of the practice, but upon the value of patient referrals to Gambro dialysis clinics generated by (or expected to be generated by) the practice.

139. In all of the new practices and some of the established ones, physician compensation is much higher than the fair market value of the services provided within the practice. In many GNS practices, expenses (paid by GNS) actually exceed income.

140. Virtually all dialysis patients from GNS practices are referred to and receive dialysis at Gambro dialysis centers.

141. In most cases, physicians from GNS practices serve as medical directors for the local Gambro dialysis facilities.

142. Because it determines physicians compensation based upon the volume and value of referrals and because the compensation exceeds the fair market value of the practice, Gambro has a "financial relationship" with physicians in GNS

practices and, therefore, under 42 U.S.C. §1395nn, may not bill Medicare for services furnished pursuant to referrals from such nephrologists.

143. Gambro violated 31 U.S.C. §3729 in that it knowingly submitted false claims to Medicare for Services for which it was not permitted to bill under 42 U.S.C. §1395nn.

144. As a result of its violation of 31 U.S.C. §3729 resulting in impermissible billing for services rendered to patients referred by physicians with whom it has a financial relationship, Gambro falsely bills Medicare for approximately $20,000,000.00 per year.

WHEREFORE, Relator Steven J. Bander, M.D. prays that this Court:

(1) Assess a civil penalty of not more than $15,000.00 against defendant Gambro for each and every prohibited financial transaction in exchange for referrals as set forth herein, as provided by 42 U.S.C. §1395nn;

(2) Assess a civil penalty against defendant Gambro of not more than $100,000.00 for each nephrologist contract that has a principal purpose of assuring referrals, as provided by 42 U.S.C. §1395nn;

(3) Assess a civil penalty of not less than $5500.00 and not more than $11,000.00 against defendant Gambro for each and every false claim set forth herein, as provided by 31 U.S.C. §3729(a);

(4) Award damages in the sum of three times the amount fraudulently billed to Medicare as set forth herein, as provided by 31 U.S.C. §3729(a) and 42 U.S.C. §1395nn, plus interest;

(5) Award him reasonable expenses, attorneys' fees and costs, as provided by 31 U.S.C. §3730(d);

(6) Exclude Gambro from participation in federal health care programs; and

(7) For such other and further relief as this Court deems just and proper.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 30th day of November, 2004 a copy of this Second Amended Complaint was served by hand delivery on Ms. Claire M. Schenk, Assistant United States Attorney, Eastern District of Missouri, 111 South Tenth Street, St. Louis, Missouri 63102.